IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC, Plaintiffs, v. COREVALVE, INC. and MEDTRONIC COREVALVE LLC, Defendants.	C.A. No. 08-91 (GMS) REDACTED - PUBLIC VERSION

DECLARATION OF LARRY WOOD IN REPLY TO COREVALVE'S OPPOSITION TO EDWARDS' MOTION FOR PERMANENT INJUNCTION

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Larry Wood, pursuant to 28 U.S.C. § 1746, declares as follows:

Background

1. I am the Corporate Vice President responsible for Transcatheter Heart Valves at Edwards Lifesciences.

2. I reviewed the declarations of Professor Haim Danenberg, Dr. Stephen JD Brecker, Dr. Ian Meredith, Dr. Daniel Blackman and Dr. Bernard Reimers, which I understand were submitted in support of CoreValve's opposition to Edwards Lifesciences' motion for permanent injunction. I have also reviewed a redacted version of CoreValve's brief in opposition to Edwards' request for an injunction and those portions of the CoreValve Appendix that did not contain CoreValve confidential information. I submit this Declaration in response to various arguments and statements made in those CoreValve declarations and its brief.

3. I attended and testified at the trial in this case in March-April 2010.

4. I have personal knowledge of the facts set forth herein, and if called upon to do so could testify to these facts under oath.

Irreparable Harm

5. CoreValve, Edwards' only competitor in the transcatheter heart valve (THV) market, launched its ReValving System before the SAPIEN device was launched. As a result, Edwards lost sales and goodwill. The advantages CoreValve obtained in reaching centers and doctors first continues today. (Wood Trial Tr. at 520:17 - 521:1 [D.I. 328]). In addition, once trained on the CoreValve device, there are certain doctors that will not want to also be trained on the Edwards device, or will not use the Edwards device in any significant volume. This lasting CoreValve advantage is shown by the CoreValve doctor declarations.

6. In addition, Edwards would be more reluctant to make significant investments in medical innovation if infringers were allowed to infiltrate the market. As I testified at trial:

> To bring these products to market takes a large investment. And, again, you are doing all this iterative work and it's very, very expensive. So you have to believe that once you commercialize that product that you're going to be able to make a return on your investment for that. If someone could wait until you did all the heavy lifting and did all the design work and then they could just copy your design and bring it to market, they would come to market without any of that initial investment and could cut your price or do other things. If that happened, then you couldn't afford to make these investments in medical innovation and you couldn't run a business that way.

(Wood Trial Tr. at 454:15 – 455:3 [D.I. 327]).

SAPIEN XT

7. The SAPIEN XT device launched commercially in March of 2010, after receiving CE Mark approval.

8. Given the smaller profile of the SAPIEN XT device compared to SAPIEN, the SAPIEN XT device can now be used transfemorally for the same patient population (based on femoral artery size) as the CoreValve ReValving System.

[redacted]

29 mm SAPIEN XT (Large Annulus)

11. As I testified at trial and at deposition, Edwards estimated the percentage of the patient population that has an annulus size of greater than 25 mm (which the current commercial Edwards products cannot treat) between 10-15%. (Wood Trial Tr. at 489:14-24, 493:23-494:4, 564:17-25). CoreValve's statement that I testified that the large annulus population is "at least 15%" is inaccurate (CoreValve Brief ("CV Br.") [D.I. 392] at 4), and does not reflect Edwards' estimate of this patient population size. (Wood Trial Tr. at 489:14-24, 493:23 - 494:4; 564:17-25; [redacted]

12. At trial Dr. Gregory Leonard testified:

> Q. Again, have you created a demonstrative to explain what you did to net out those sales?
>
> A. I have, yes.

...

... physical limitations that we need to worry about. One is the annulus size or the valve size adjustment. So we heard there are certain patients that have an annulus that is too big for the Edwards product. And Mr. Wood testified that that number was somewhere between 10 and 15 percent of patients.

I actually -- you know, that turns out to be a pretty good estimate, because, in this case, the data was produced on CoreValve patients and what their annulus size was. And if you go look at that data and ask what percentage had an annulus greater than 25 millimeters, the answer turns out to be 10.4 percent. So Mr. Wood was pretty much dead on.

(Leonard Trial Tr. at 958:14-959:23 [D.I. 329]).

[redacted]

Safety of the Edwards' Devices

15. CoreValve's suggestions in its brief that the CoreValve ReValving System is a safer device than the Edwards SAPIEN and SAPIEN XT devices (CV Br. at 5, 14) are not supported by the data of which I am aware.

16. For example, the French Registry is a registry sponsored by the French Government to study the results of transcatheter aortic valve implantation procedures "according to the current clinical indications." (*See* PTX 2123 at 3 (FRANCE Registry), attached as Ex. 2). Edwards did not participate in the collection or analysis of the data; this was a government project. The French Registry is important because it provides data on real world usage of THV products. The data came from 16 centers across France, and comprised 244 consecutive patients from February 1 to September 31, 2009.

17. The French Registry shows the following:[1]

	Edwards TF (n=95)	**CoreValve TF (n=66)**	**Edwards TA (n=71)**	**CoreValve SC (n=12)**
30 Day Mortality	8.4%	15.1%	16.9%	8.3%
Coronary Occlusion	2.1%	1.5%	0	0
New Pacemaker	5.3%	27.2%	4.2%	25%
Vascular Complications	5.2%	7.5%	7.0%	8.3%

(PTX 2123 at 13 (FRANCE Registry), attached as Ex. 2).

18. The SAPIEN TF has a much lower 30 day mortality rate than the CoreValve TF. The rates of coronary occlusion are similar, as are the rates of vascular complications. While these differences are not statistically significant, they certainly do not support the conclusion that the CoreValve device is safer. The need for new pacemaker implantation is statistically significantly different with CoreValve having a much higher rate.

19. CoreValve also states that there is an increased risk of renal failure with the Edwards devices. I am not aware of data that supports this conclusion. The Edwards SOURCE registry reported data of consecutive patient implants in the first year of

[1] "TF" means transfemoral; "TA" means transapical; "SC" means subclavian.

SAPIEN commercialization from 32 sites. The purpose of the SOURCE registry was to assess the SAPIEN device as it was rolled out commercially. The SOURCE registry reports post-implantation renal failure at a rate of 4.3%. (*See* Martyn Thomas *et al.*, "Thirty Day Results of the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry," *Circulation*, Vol. 122, No. 1, pp. 62-69 at 64-65 (July 6, 2010), attached as Ex. 3). The rate of renal failure is 7.1% for the TA approach and only 1.3% for the TF approach. *Id.*

Ability to Train Centers to Treat Patients

20. To date, Edwards has trained over 240 sites worldwide in the use of the SAPIEN and SAPIEN XT devices. To date, Edwards has also been able to exceed projections and train more physicians than anticipated. (Wood Trial Tr. at 519:4-18). As I testified to [redacted] and at trial, Edwards has the "capabilities and capacity to train a large number of centers." (Wood Trial Tr. at 587:6-7; 587:12-17; [redacted]

[redacted]

21. I disagree with the declaration of Dr. Ian Meredith, which states that Edwards does not have the ability to train doctors and centers in Australia. [redacted]

[redacted]

22. I disagree with the assertion that if CoreValve were removed from the market patients would be left with no alternative. Those patients could be referred to centers for SAPIEN and SAPIEN XT implants.

23. Additionally, Edwards could move aggressively to train centers previously implanting CoreValve devices. [redacted]

[redacted]

[redacted]

Field Safety Notices

27. CoreValve states in its brief that "it is clear [] there are [safety] issues with Sapien." (CV Br. at 14). As purported support, CoreValve cites to two Edwards Field Safety Notices. (CV Br. at 14 (citing CV App. at A408-14 (Field Safety Notices))).

28. The April 1 and April 12, 2010 Field Safety Notices cited by CoreValve are two versions of the same Field Safety Notice. Both Notices address the screw-on cap of the Ascendra delivery system, which is Edwards' transapical delivery system. Neither Notice is directed to the SAPIEN valve. Instructions provided by Edwards describe how to use this cap. If the cap is not screwed on tight, blood can leak out. These Notices caution and remind the doctors to follow the instructions provided with the device, as well as their training (to screw on the cap tightly when used), and advise of what will happen "[i]f the instructions . . . are not [ ] followed . . . ." (CV App. at A408 (Edwards Field Safety Notice)).

The CoreValve Instructions for Use

32. I wish to address several of the statements made in CoreValve's briefs, and its corresponding citations to doctor declarations, about off-label uses of the ReValving System or uses contradicted by the ReValving System's approved label.

33. For example, CoreValve suggests that it can implant its device without the need for surgical support. (CV Br. at 5). This is contrary to CoreValve's own Instructions for Use. Section 2.1 of CoreValve's Instructions for Use, which pertains to the general "Warning and Precautions" of using the CoreValve ReValving System, states that "[t]his procedure should only be performed where emergency aortic valve surgery can be performed promptly." (PTX 23 at 2 (Instructions for Use), attached as Ex. 6).

34. CoreValve also refers to the repositionability and retrievability of the ReValving System. (CV App. at A419, ¶ 10 (Danenberg Decl.); *Id.* at A422, ¶ 7 (Brecker Decl.); *Id.* at A666, ¶ 8 (Reimer Decl.)). However, the CoreValve Instructions for Use itself is at odds with several of the statements made in the doctor declarations.

Specifically, section 2.3 of CoreValve's Instructions for Use, which also pertains to the general "Warning and Precautions" of using the CoreValve ReValving System, states that "[o]nce deployment has been initiated, retrieval of the Bioprosthesis is not possible. Attempted retrieval (i.e., use of a guide wire, snare and/or forceps) may cause aortic root, coronary artery, and/or myocardial damage. If necessary, the Bioprosthesis can be repositioned proximally – **only** if the frame has been deployed no more than 10% of its length. **No attempt should be made to reposition the Bioprosthesis by advancing it distally.**" (PTX 23 at 2 (Instructions for Use), attached as Ex. 6 (emphasis original)).

35. As a result, the purported benefits of retrievability and repositionability discussed in CoreValve's brief and doctor declarations are directly contradicted by CoreValve's own approved Instructions for Use.

36. CoreValve also cites possible use of its product to treat aortic regurgitation and by a subclavian approach. (CV Br. at 4, 13; CV App. at A418, ¶ 7 (Danenberg Decl.); *id.* at A423, ¶ 10 (Brecker Decl.); *id.* at A426, ¶ 8 (Meredith Decl.)). According to CoreValve's Instruction for Use, use of the CoreValve ReValving System to treat aortic regurgitation or by subclavian approach is off-label.

Competitors

37. [redacted] The declaration of Teresa Muckala makes reference to potential competitors in the THV market. (CV App. at A437, ¶ 5). The declaration goes on to identify Sorin as a company that is going to receive CE Mark approval in 2010, and begin commercialization in 2011. (*Id.* at A437, ¶ 6). I reviewed the Sorin presentation attached to the declaration (CV App. at A609-61), and see no

mention of any THV technology. The heart valves set forth in the Sorin presentation are all surgical in nature, not transcatheter. In particular, it appears that the heart valve being referenced in the Muckala declaration is the Sorin Perceval S, a surgical valve which requires a traditional open heart surgical approach.

[redacted]

Edwards' Refusal to License the '552 Patent

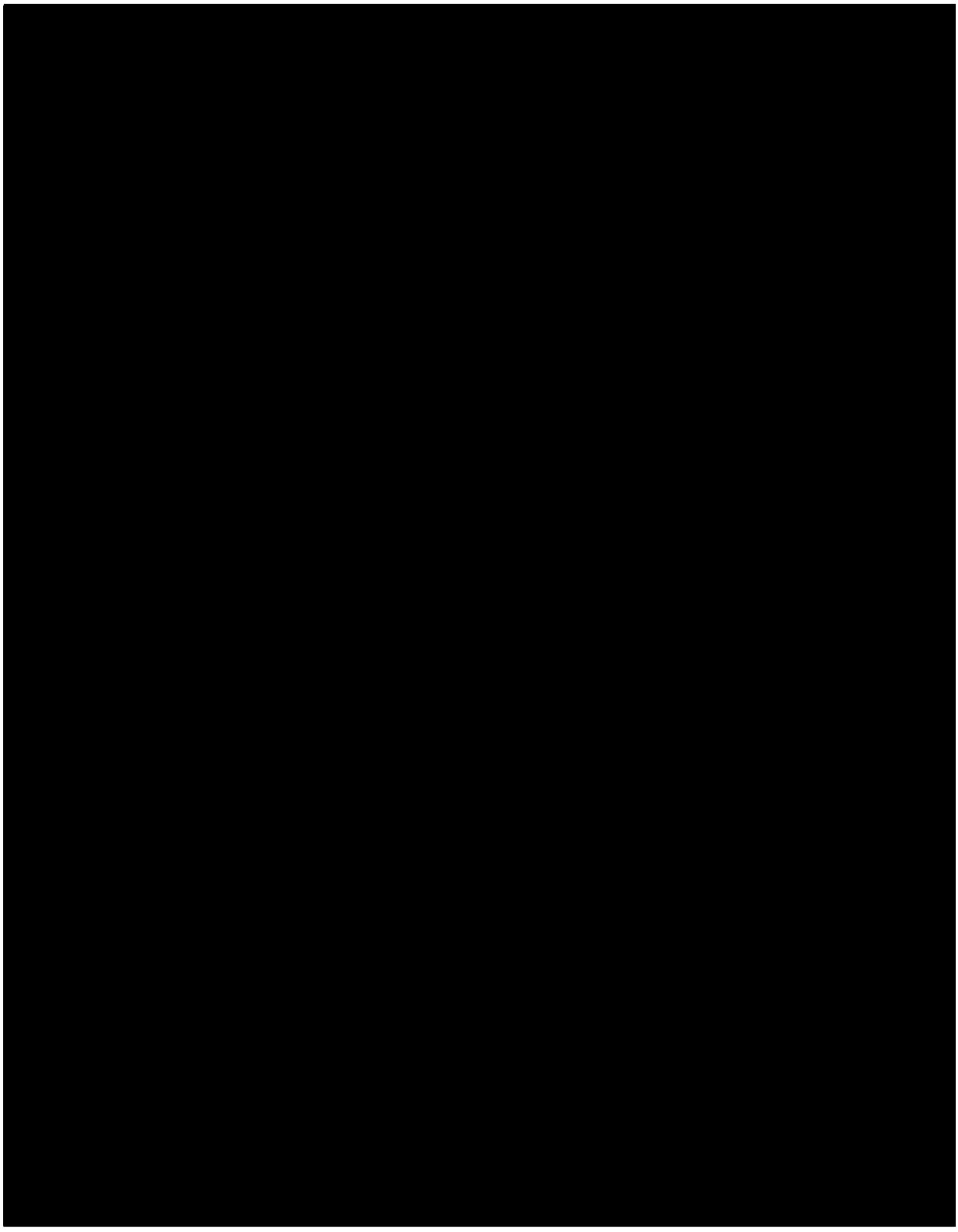
39. Edwards has made every effort to protect its exclusivity in the '552 Patent in the field of transcatheter heart valves, particularly for transfemoral applications. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]



I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on August 16, 2010
Irvine, California

Larry Wood

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2010 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

John W. Shaw, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP

I further certify that I caused copies of the foregoing document to be served on August 17, 2010 upon the following in the manner indicated:

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